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NOV 20 2001

Charles E. Van Horn, Esq.
Finnegan Henderson Farabow Garrett & Dunner
1300 I Street NW
Washington DC 20005-3315

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,746,680

#29

Dear Mr. Van Horn:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,746,680 for a period of five years. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). For your convenience, a copy of the patent submission sample format (downloaded from FDA's internet web page) with the address for the Orange Book is enclosed.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Patent term extension certificate
Patent Submission Sample Format

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

FDA Docket No.: 98E-0755

Patent Submission Sample Format

This is a format suggestion for submission of patent information for NDAs submitted under section 505 of the Federal Food Drug and Cosmetic Act. For more detailed information please refer to 21 C.F.R. 314.53.

Time Sensitive Patent Information pursuant to 21 C.F.R. 314.53 for NDA #_____

The following is provided in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984:

Trade Name:
Active Ingredient(s):
Strength(s):
Dosage Form:
Approval Date:

A. This information should be provided for each individual patent submitted.

U.S. Patent Number:

Expiration Date:

Type of Patent--Indicate all that apply:

Drug Substance(Active Ingredient) ___Y ___N
Drug Product(Composition/Formulation) ___Y ___N
Method of Use ___Y ___N

a. If patent claims method(s) of use, please specify approved method(s)of use or method(s) of use for which approval is being sought that are covered by patent:_____

Name of Patent Owner:

U.S. Agent (if patent owner or applicant does not reside or have place of business in the US):

B. The following declaration statement is required by 21CFR 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Patent Number _____ covers the composition, formulation and/or method of use of _____(name of drug product). This product is:

___currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act)

OR

___the subject of this application for which approval is being sought.)

Signed:

Date:

Title (optional):

Telephone Number (optional):

The above information should be submitted to the NDA with the original application or as correspondence to an existing NDA. For patents issued after the NDA is filed or approved, the applicant is required to submit the information within 30 days of the date of issuance of the patent.

To expedite publication in the The Orange Book,* the above information may be provided to the Division of Data Management and Services at the address below. You may also contact the Division of Data Management and Services directly at (301)827-5467 regarding listing of patent information.

Mailing address: (US Mail)
U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services
Information Services Team
HFD-93
5600 Fishers Lane
Rockville, MD 20857

OR

Location address: (for FedEx deliveries)
U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services
Information Services Team
HFD-93 Room #3012
12420 Parklawn Drive
Rockville, Maryland 20857-0001

OR faxed to: (301)-594-6463

* - Please note that patents for unapproved compositions, formulations, or uses will NOT be published in the The Orange Book.

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

(68)	PATENT NO.	:	4,746,680
(45)	ISSUED	:	May 24, 1988
(75)	INVENTOR	:	James E. Jeffery, et al.
(73)	PATENT OWNER	:	Knoll Aktiengesellschaft
(95)	PRODUCT	:	MERIDIA® (sibutramine hydrochloride)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 4,746,680 based upon the regulatory review of the product MERIDIA® (sibutramine hydrochloride) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) Five years

from June 11, 2002, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

I have caused the seal of the Patent and Trademark Office to be affixed this 14th day of November 2001.

Nicholas P. Godici

Nicholas P. Godici
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office